WE CLAIM

1. A process for the preparation of water-dispersible tablets of cephalexin, wherein the tablets disintegrate within 3 minutes in water at 20°C± 5°C to form a uniform suspension, comprising granulating cephalexin, disintegrant and colloidal silicon dioxide with binder solution to form granules; drying the resulting granules; mixing the dried granules with disintegrant(s), fillers, lubricating agents and optionally other excipients; and compressing to form tablets.

2. The process according to claim 1 wherein the granules comprise a suspending agent and/or coloring agent.

3. The process according to claim 1 wherein other optional excipients comprise one or more of antiadherants, sweeteners, coloring agents and flavoring agents.

4. The process according to claim 1 where cephalexin is present as monohydrate.

5. The process according to claim 1 wherein cephalexin has a particle size d_{90} less than 250μm.

6. The process according to claim 1 wherein granulation is the wet granulation method.

7. The process according to claim 1 wherein the disintegrant(s) are selected from sodium starch glycolate, carboxy methylcellulose, croscarmellose sodium and crospovidone and combinations thereof.

8. The process according to claim 7 wherein the disintegrant is crospovidone.

9. The process according to claim 1 wherein the disintegrant is present in an amount from about 0.5% to about 10% by weight of the total tablet weight.

10. The process according to claim 1 wherein the binder is selected from hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone and combinations thereof.

11. The process according to claim 10 wherein the binder is polyvinyl pyrrolidone.

12. The process according to claim 1 wherein the binder is present in an amount from about 0.25% to about 4% by weight of the total tablet weight.

13. The process according to claim 1 wherein the filler is selected from lactose, microcrystalline cellulose, mannitol and combinations thereof.

14. The process according to claim 13 wherein the filler is mannitol.

15. The process according to claim 13 wherein the filler is microcrystalline cellulose.

16. The process according to claim 1 wherein the lubricants of the present invention may be selected from magnesium stearate, stearic acid , sodium stearyl fumarate and combinations thereof.

17. The process according to claim 16 wherein the lubricant is magnesium stearate.

18. The process according to claim 1 wherein the lubricant is in the amount of about 0.25% to about 5% weight of the total tablet weight.

19. The process according to claim 2 wherein the suspending agent is selected from microcrystalline cellulose, sodium carboxy methylcellulose, colloidal silicon dioxide, mannitol, povidone, sodium starch glycolate or a combination thereof.

20. The process according to claim 19 wherein the suspending agent is colloidal silicon dioxide.

21. The process according to claim 2 wherein the suspending agent is present in an amount of about 0.25% to about 6.0% by weight of the total tablet weight.

22. The process according to claim 3 wherein the coloring agent is D&C Yellow Aluminum Lake.

23. The process according to claim 3 wherein the antiadherant is colloidal silicon dioxide.

24. The process according to claim 3 wherein the sweetening agent is selected from sugars, saccharin or its salts, aspartame or combinations thereof.

25. The process according to claim 24 wherein sweetening agent is aspartame.

26. The process according to claim 3 wherein sweetening agent is present in an amount of about 0.01% to about 2.0% by weight of total weight of tablet.

27. The process according to claim 3 wherein the flavoring agent is Flavor Peppermint.

28. A water dispersible dosage form of cephalexin comprising an intragranular portion and an extragranular portion:

the intragranular portion comprising a pharmaceutically acceptable amount of cephalexin or its salts, a disintegrant(s), and a suspending agent(s); and

the extragranular portion comprising one or more pharmaceutically acceptable excipients.

29. The water dispersible dosage form of claim 28 wherein cephalexin is present as a monohydrate.

30. The water dispersible dosage form of claim 28 wherein cephalexin has a particle size of d_{90} less than 250μm.

31. The water dispersible dosage form of claim 28 wherein the pharmaceutically acceptable excipients comprise one or more of fillers, binders, lubricants, antiadherants, sweeteners, coloring agents, and flavoring agents.

32. The water dispersible dosage form of claim 28 wherein the disintegrant(s) are selected sodium starch glycolate, carboxy methylcellulose, croscarmellose sodium and crospovidone and combinations thereof.

33. The water dispersible dosage form of claim 32 wherein the disintegrant is crospovidone.

34. The water dispersible dosage form of claim 28 wherein the disintegrant is present in an amount from about 0.5% to about 10% by weight of the total tablet weight.

35. The water dispersible dosage form of claim 31 wherein the binder comprises one or more of hydroxpropyl cellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone and combinations thereof.

36. The water dispersible dosage form of claim 35 wherein the binder is polyvinyl pyrrolidone.

37. The water dispersible dosage form of claim 31 wherein the binder is present in an amount from about 0.25% to about 4% by weight of total tablet weight.

38. The water dispersible dosage form of claim 31 wherein the filler comprises one or more of lactose, microcrystalline cellulose, mannitol, and combinations thereof.

39. The water dispersible dosage form of claim 38 wherein the filler is mannitol.

40. The water dispersible dosage form of claim 38 wherein the filler is microcrystalline cellulose.

41. The water dispersible dosage form of claim 31 wherein the lubricants of the present invention may be selected from magnesium stearate, stearic acid, sodium stearyl fumarate and combinations thereof.

42. The water dispersible dosage form of claim 41 wherein the lubricant is magnesium stearate.

43. The water dispersible dosage form of claim 31 wherein the lubricant is in the amount of about 0.25% to about 5% weight of the total tablet weight.

44. The water dispersible dosage form of claim 28 wherein the suspending agent is selected from microcrystalline cellulose, sodium carboxy methylcellulose, colloidal silicon dioxide, mannitol, povidone, sodium starch glycolate or a combination thereof.

45. The water dispersible dosage form of claim 44 wherein the suspending agent is colloidal silicon dioxide.

46. The water dispersible dosage form of claim 28 wherein the suspending agent is present in an amount of about 0.25% to about 6.0% by weight of the total tablet weight.

47. The water dispersible dosage form of claim 31 wherein the coloring agent is D&C Yellow Aluminum Lake.

48. The water dispersible dosage form of claim 31 wherein the antiadherant is colloidal silicon dioxide.

49. The water dispersible dosage form of claim 31 wherein the sweetening agent is selected from sugars, saccharin or its salts, aspartame or combinations thereof.

50. The water dispersible dosage form of claim 49 wherein sweetening agent is aspartame.

51. The water dispersible dosage form of claim 31 wherein sweetening agent is present in an amount of about 0.01% to about 2.0% by weight of total weight of tablet.

52. The water dispersible dosage form of claim 31 wherein the flavoring agent is Flavor Peppermint.

53. A method of treating an infection in a human caused by microorganisms susceptible to cephalexin comprising providing cephalexin in the form of the water dispersible tablet of claim 29.